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(56) **References Cited**

U.S. PATENT DOCUMENTS

4,425,919 A 1/1984 Alston, Jr. et al.
4,563,181 A 1/1986 Wijayarathna et al.

(Continued)

FOREIGN PATENT DOCUMENTS

EP 0 277 368 8/1988
EP 0 414 350 2/1991

(Continued)

OTHER PUBLICATIONS

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(Continued)

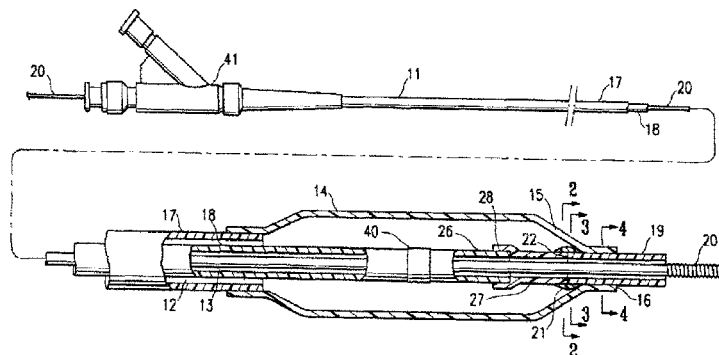
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(57) **ABSTRACT**

Balloon catheter includes an elongate tubular shaft having an outer tubular member having proximal and distal portions, and an inner tubular member having a distal length extending distally from the distal portion of the outer tubular member. The elongate tubular shaft has an inflation lumen and a guidewire lumen defined therein. The guidewire lumen extends along at least the distal length of inner tubular member. The balloon catheter also includes a distal end section coupled to a distal end of the inner tubular member and having a proximal end and a distal end. The balloon catheter also includes a balloon having a proximal portion sealingly coupled to the distal portion of the outer tubular member, a distal portion sealingly coupled to the distal end section, and a working length therebetween. The balloon defines an inner chamber. The proximal end of the distal end section is disposed within the inner chamber.

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(56)

References Cited

U.S. PATENT DOCUMENTS

4,596,563 A 6/1986 Pande
4,775,371 A 10/1988 Mueller, Jr.
4,820,349 A 4/1989 Saab
4,877,031 A 10/1989 Conway et al.
4,886,506 A 12/1989 Lovgren et al.
4,892,519 A 1/1990 Songer et al.
4,952,357 A 8/1990 Euteneuer
4,955,895 A 9/1990 Sugiyama et al.
4,960,410 A 10/1990 Pinchuk
4,976,720 A 12/1990 Machold et al.
4,994,047 A 2/1991 Walker et al.
5,047,045 A 9/1991 Arney et al.
5,061,273 A 10/1991 Yock
5,078,702 A 1/1992 Pomeranz
5,085,649 A 2/1992 Flynn
5,112,304 A 5/1992 Barlow et al.
5,156,594 A 10/1992 Keith
5,176,661 A 1/1993 Evard et al.
5,195,969 A 3/1993 Wang et al.
5,205,822 A 4/1993 Johnson et al.
5,207,700 A 5/1993 Euteneuer
5,217,434 A 6/1993 Arney
5,217,482 A 6/1993 Keith
5,250,059 A 10/1993 Andreas et al.
5,270,086 A 12/1993 Hamlin
5,277,199 A 1/1994 DuBois et al.
5,290,232 A 3/1994 Johnson et al.
5,290,306 A 3/1994 Trotta et al.
5,300,025 A 4/1994 Wantink
5,304,134 A 4/1994 Kraus et al.
5,312,430 A 5/1994 Rosenbluth et al.
5,318,032 A 6/1994 Lonsbury et al.
5,318,526 A 6/1994 Cohen
5,334,146 A 8/1994 Ozasa
5,342,386 A 8/1994 Trotta
5,358,486 A 10/1994 Saab
5,364,357 A 11/1994 Aase
5,370,616 A 12/1994 Keith et al.
5,378,238 A * 1/1995 Peters A61M 25/0054
604/103.1
5,395,336 A 3/1995 Barclay et al.
5,425,712 A 6/1995 Goodin
5,447,497 A 9/1995 Sogard et al.
5,451,233 A 9/1995 Yock
5,454,789 A * 10/1995 Burns A61M 25/0075
604/99.04
5,470,315 A 11/1995 Adams
5,476,477 A 12/1995 Burns
5,478,320 A 12/1995 Trotta
5,484,409 A * 1/1996 Atkinson A61M 25/0023
604/103.03
5,490,837 A 2/1996 Blaeser et al.
5,496,275 A 3/1996 Sirhan et al.
5,499,980 A 3/1996 Euteneuer
5,507,766 A 4/1996 Kugo et al.
5,512,051 A 4/1996 Wang et al.
5,526,823 A 6/1996 Wheeler et al.
5,538,510 A 7/1996 Fontirroche et al.
5,538,513 A 7/1996 Okajima
5,538,918 A 7/1996 Haase et al.
5,545,134 A 8/1996 Hilaire et al.
5,549,552 A 8/1996 Peters et al.
5,554,121 A 9/1996 Ainsworth et al.
5,556,383 A 9/1996 Wang et al.
5,569,195 A 10/1996 Saab
5,587,125 A 12/1996 Roychowdhury
5,599,326 A 2/1997 Carter
5,613,979 A 3/1997 Trotta et al.
5,620,649 A 4/1997 Trotta

5,622,665 A 4/1997 Wang
5,625,202 A 4/1997 Chai
5,632,760 A 5/1997 Sheiban et al.
5,643,209 A 7/1997 Fugoso et al.
5,658,264 A 8/1997 Samson
5,661,074 A 8/1997 Tischler
5,690,613 A 11/1997 Verbeck
5,728,063 A 3/1998 Preissman et al.
5,732,098 A 3/1998 Nisitani et al.
5,743,874 A 4/1998 Fischell et al.
5,743,875 A 4/1998 Sirhan et al.
5,749,849 A 5/1998 Engelson
5,755,690 A 5/1998 Saab
5,759,173 A 6/1998 Preissman et al.
5,766,151 A 6/1998 Valley et al.
5,769,817 A 6/1998 Burgmeier
5,769,819 A 6/1998 Schwab et al.
5,775,327 A 7/1998 Randolph et al.
5,779,731 A 7/1998 Leavitt
5,782,811 A 7/1998 Samson et al.
5,791,036 A 8/1998 Goodin et al.
5,792,124 A 8/1998 Horrigan et al.
5,792,144 A 8/1998 Fischell et al.
5,795,325 A 8/1998 Valley et al.
5,795,341 A 8/1998 Samson
5,797,887 A 8/1998 Rosen et al.
5,804,834 A 9/1998 Shimoyama et al.
5,814,016 A 9/1998 Valley et al.
5,820,594 A 10/1998 Fontirroche et al.
5,821,569 A 10/1998 Dutta
5,833,657 A 11/1998 Reinhardt et al.
5,853,400 A 12/1998 Samson
5,874,747 A 2/1999 Redwing et al.
5,879,369 A 3/1999 Ishida
5,879,499 A 3/1999 Corvi
5,889,805 A 3/1999 Botez et al.
5,902,290 A 5/1999 Peacock et al.
5,908,406 A 6/1999 Ostapchenko et al.
5,911,715 A 6/1999 Berg et al.
5,916,193 A 6/1999 Stevens et al.
5,947,939 A 9/1999 Mortier et al.
5,964,778 A 10/1999 Fugoso et al.
5,989,218 A 11/1999 Wasicek
6,004,289 A 12/1999 Saab
6,004,339 A 12/1999 Wijay
6,010,521 A 1/2000 Lee et al.
6,021,340 A 2/2000 Randolph et al.
6,024,693 A 2/2000 Schock et al.
6,024,722 A 2/2000 Rau et al.
6,027,510 A 2/2000 Alt
6,036,670 A 3/2000 Wijeratne et al.
6,056,719 A 5/2000 Mickley
6,059,751 A 5/2000 Ostapchenko et al.
6,059,770 A 5/2000 Peacock et al.
6,071,266 A 6/2000 Kelley
6,086,556 A 7/2000 Hamilton et al.
6,102,890 A 8/2000 Stivland et al.
6,124,007 A 9/2000 Wang et al.
6,132,824 A 10/2000 Hamlin
6,136,258 A 10/2000 Wang et al.
6,146,356 A 11/2000 Wang et al.
6,165,166 A * 12/2000 Samuelson A61M 25/0009
604/524
6,165,195 A 12/2000 Wilson et al.
6,168,588 B1 1/2001 Wilson
6,171,275 B1 1/2001 Webster, Jr. et al.
6,171,278 B1 1/2001 Wang et al.
6,179,810 B1 1/2001 Wantink et al.
6,179,856 B1 1/2001 Barbere
6,193,686 B1 2/2001 Estrada et al.
6,197,015 B1 3/2001 Wilson
6,210,396 B1 4/2001 MacDonald et al.
6,217,547 B1 4/2001 Lee
6,217,565 B1 4/2001 Cohen
6,242,063 B1 6/2001 Ferrera et al.
6,245,053 B1 6/2001 Benjamin
6,251,093 B1 6/2001 Valley et al.
6,264,683 B1 7/2001 Stack et al.
6,265,016 B1 7/2001 Hostettler et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

6,306,097	B1	10/2001	Park et al.	7,947,059	B2	5/2011	Chin et al.	
6,306,124	B1	10/2001	Jones et al.	8,012,300	B2	9/2011	Simpson et al.	
6,308,342	B1	10/2001	Qi	8,052,638	B2	11/2011	Lee et al.	
6,358,227	B1	3/2002	Ferrera et al.	8,070,719	B2	12/2011	Lee et al.	
6,364,894	B1	4/2002	Healy et al.	8,382,738	B2	2/2013	Simpson et al.	
6,402,720	B1	6/2002	Miller et al.	8,388,602	B2	3/2013	Wilson et al.	
6,416,494	B1	7/2002	Wilkins	8,403,885	B2	3/2013	Arana et al.	
6,482,348	B1	11/2002	Wang et al.	8,444,608	B2	5/2013	Haslinger et al.	
6,495,090	B1	12/2002	Wilkins et al.	8,613,722	B2	12/2013	Lee et al.	
6,495,127	B1	12/2002	Wallace et al.	8,657,782	B2	2/2014	Arana et al.	
6,500,148	B1	12/2002	Pinchuk et al.	8,721,624	B2	5/2014	Wilson et al.	
6,508,784	B1	1/2003	Shu	9,023,174	B2	5/2015	Simpson et al.	
6,530,938	B1	3/2003	Lee et al.	9,056,190	B2	6/2015	Simpson et al.	
6,548,010	B1	4/2003	Stivland et al.	9,205,223	B2	12/2015	Wilson et al.	
6,575,934	B2	6/2003	Duchamp	9,216,274	B2*	12/2015	Arana	A61M 25/0054
6,575,958	B1	6/2003	Happ et al.	2001/0001812	A1	5/2001	Valley et al.	
6,579,259	B2	6/2003	Stevens et al.	2001/0016702	A1	8/2001	Benjamin	
6,585,687	B1	7/2003	Shkolnik	2001/0029362	A1	10/2001	Sirhan et al.	
6,585,688	B2	7/2003	Ferrera et al.	2001/0037085	A1	11/2001	Keith et al.	
6,589,207	B1	7/2003	El-Nounou	2002/0014631	A1	2/2002	Iwata et al.	
6,589,226	B1	7/2003	Owens	2002/0018866	A1	2/2002	Lee et al.	
6,591,472	B1	7/2003	Noone et al.	2002/0031153	A1	3/2002	Niwa et al.	
6,603,147	B1	8/2003	Hashimoto et al.	2002/0053676	A1	5/2002	Kozaki	
6,620,127	B2	9/2003	Lee et al.	2002/0072755	A1	6/2002	Bigus et al.	
6,620,128	B1	9/2003	Simhambhatla	2002/0082637	A1	6/2002	Lumauig	
6,626,889	B1	9/2003	Simpson et al.	2002/0165523	A1	11/2002	Chin et al.	
6,629,961	B1	10/2003	Israelsson et al.	2003/0009151	A1	1/2003	Wang	
6,645,422	B2	11/2003	Jung, Jr. et al.	2003/0028234	A1*	2/2003	Miller	A61M 25/10 623/1.11
6,648,854	B1	11/2003	Patterson et al.	2003/0032920	A1	2/2003	Wantink	
6,663,614	B1	12/2003	Carter	2003/0055447	A1	3/2003	Lee et al.	
6,673,291	B1	1/2004	Field et al.	2003/0105426	A1	6/2003	Jorgensen	
6,673,302	B2	1/2004	Wang et al.	2003/0125712	A1	7/2003	Zhou	
6,695,809	B1	2/2004	Lee	2003/0139762	A1	7/2003	Lee	
6,702,802	B1	3/2004	Hancock et al.	2004/0059291	A1	3/2004	McDonnell et al.	
6,718,211	B2	4/2004	Smits	2004/0059292	A1	3/2004	Hisamatsu et al.	
6,733,487	B2	5/2004	Keith et al.	2004/0064130	A1	4/2004	Carter	
6,756,094	B1	6/2004	Wang et al.	2004/0068240	A1	4/2004	Goodin et al.	
6,777,644	B2	8/2004	Peacock et al.	2004/0087901	A1	5/2004	Rice et al.	
6,793,647	B1	9/2004	Cryer et al.	2004/0097892	A1	5/2004	Evans et al.	
6,796,958	B2	9/2004	Chen et al.	2004/0131808	A1	7/2004	Schoenle et al.	
6,796,960	B2	9/2004	Cioanta et al.	2004/0167441	A1	8/2004	Reynolds et al.	
6,835,189	B2	12/2004	Musbach et al.	2004/0170782	A1	9/2004	Wang et al.	
6,837,890	B1	1/2005	Chludzinski et al.	2004/0173935	A1	9/2004	Lim et al.	
6,863,678	B2	3/2005	Lee et al.	2004/0181206	A1	9/2004	Chiu et al.	
6,875,197	B1	4/2005	Simhambhatla et al.	2004/0191443	A1	9/2004	Hamlin	
6,887,219	B2	5/2005	Wantink	2004/0215141	A1	10/2004	Clarke et al.	
6,890,395	B2	5/2005	Simhambhatla	2004/0267195	A1	12/2004	Currin	
6,893,456	B2	5/2005	Lumauig	2004/0267280	A1	12/2004	Nishide et al.	
6,911,038	B2	6/2005	Mertens et al.	2005/0015048	A1	1/2005	Chiu et al.	
6,913,600	B2	7/2005	Valley et al.	2005/0043679	A1	2/2005	Devens et al.	
6,918,920	B1*	7/2005	Wang	2005/0124976	A1	6/2005	Devens, Jr. et al.	
			A61M 25/0069 606/194	2005/0131445	A1	6/2005	Holman et al.	
6,946,092	B1	9/2005	Bertolino et al.	2005/0148997	A1	7/2005	Valley et al.	
6,951,555	B1	10/2005	Suresh et al.	2005/0154414	A1	7/2005	Perreault et al.	
6,951,675	B2	10/2005	Chin et al.	2005/0186370	A1	8/2005	Hamilton et al.	
6,979,342	B2	12/2005	Lee et al.	2005/0228429	A1	10/2005	Burgmeier et al.	
7,026,026	B2	4/2006	Ferrera et al.	2005/0238833	A1	10/2005	Wang et al.	
7,029,732	B2	4/2006	Wang et al.	2005/0277878	A1*	12/2005	Lee	A61M 25/1036 604/103.04
7,037,291	B2	5/2006	Lee et al.	2006/0008606	A1	1/2006	Horn et al.	
7,037,295	B2	5/2006	Tiernan et al.	2006/0136032	A1	6/2006	Legarda et al.	
7,074,206	B2	7/2006	Lee et al.	2006/0165926	A1	7/2006	Weber	
7,108,877	B2	9/2006	Blair et al.	2006/0175739	A1	8/2006	Hession et al.	
7,112,357	B2	9/2006	Miller et al.	2006/0282041	A1	12/2006	Melzheimer et al.	
7,141,059	B2	11/2006	Duchamp et al.	2007/0060863	A1	3/2007	Goeken et al.	
7,147,817	B1	12/2006	Lim et al.	2007/0142771	A1	6/2007	Durcan	
7,163,523	B2	1/2007	Devens, Jr. et al.	2007/0167973	A1	7/2007	Stupecky et al.	
7,195,638	B1	3/2007	Sridharan	2007/0191813	A1	8/2007	Chen	
7,273,485	B2	9/2007	Simpson et al.	2007/0240817	A1	10/2007	Strong et al.	
7,335,185	B2	2/2008	Tang et al.	2007/0260177	A1	11/2007	Warnack	
7,341,571	B1	3/2008	Harris et al.	2007/0276426	A1*	11/2007	Euteneuer	A61M 25/0147 606/192
7,556,634	B2	7/2009	Lee et al.	2008/0015540	A1*	1/2008	Muni	A61B 17/24 604/500
7,662,130	B2	2/2010	Lee et al.	2008/0045895	A1	2/2008	Simpson et al.	
7,828,766	B2	11/2010	Durcan	2008/0045928	A1	2/2008	Simpson et al.	
7,833,193	B2	11/2010	Lee et al.	2008/0065188	A1	3/2008	Pallazza	
7,906,066	B2	3/2011	Wilson et al.					

(56)

References Cited**U.S. PATENT DOCUMENTS**

2008/0077085	A1*	3/2008	Eidenschink	A61M 25/10 604/96.01
2008/0221550	A1*	9/2008	Lee	A61M 25/10 604/508
2008/0262470	A1*	10/2008	Lee	A61M 25/001 604/509
2009/0005754	A1	1/2009	Soettermans	
2009/0156998	A1	6/2009	Arana et al.	
2009/0247946	A1	10/2009	Lee et al.	
2009/0264822	A1	10/2009	Johnson	
2010/0010439	A1	1/2010	Burgmeier et al.	
2010/0130925	A1	5/2010	Haslinger et al.	
2011/0315301	A1	12/2011	Simpson et al.	
2012/0065586	A1	3/2012	Lee et al.	
2012/0143129	A1	6/2012	Simpson et al.	
2012/0296273	A1	11/2012	Arana et al.	
2013/0160932	A1	6/2013	Simpson et al.	
2013/0178795	A1	7/2013	Wilson et al.	
2013/0253425	A1	9/2013	Haslinger et al.	
2014/0081310	A1	3/2014	Lee et al.	
2014/0163466	A1	6/2014	Arana et al.	
2014/0213967	A1	7/2014	Wilson et al.	

FOREIGN PATENT DOCUMENTS

EP	0 420 488	3/1991
EP	0 737 487	10/1996
EP	0 821 979	2/1998
EP	0 904 795	3/1999
EP	0 931 558	7/1999
EP	0 962 227	8/1999
EP	1 103 280	5/2001
EP	1 287 846	3/2003
JP	10-290837	11/1998
JP	2001-018290	1/2001
JP	2001-353225	12/2001
JP	2005-167638	6/2005
WO	WO 89/02763	4/1989
WO	WO 93/20882	10/1993
WO	WO 95/18647	7/1995
WO	WO 96/03175	2/1996
WO	WO 96/34646	11/1996
WO	WO 97/26027	7/1997
WO	WO 99/13924	3/1999
WO	WO 01/34240	5/2001
WO	WO 01/51115	7/2001
WO	WO 01/89621	11/2001
WO	WO 02/36194	5/2002
WO	WO 02/36196	5/2002
WO	WO 03/004248	1/2003
WO	WO 2005/021083	3/2005
WO	WO 2006/126311	11/2006
WO	WO 2007/054364	5/2007
WO	WO 2007/146572	12/2007
WO	WO 2010/141765	12/2010

OTHER PUBLICATIONS

U.S. Appl. No. 09/957,526, Jan. 24, 2005 Issue Fee payment.
 U.S. Appl. No. 09/957,526, Nov. 4, 2004 Notice of Allowance.
 U.S. Appl. No. 09/957,526, Sep. 21, 2004 Response to Non-Final Office Action.
 U.S. Appl. No. 09/957,526, Jul. 1, 2004 Non-Final Office Action.
 U.S. Appl. No. 09/957,526, Apr. 22, 2004 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 09/957,526, Feb. 17, 2004 Final Office Action.
 U.S. Appl. No. 09/957,526, Nov. 26, 2003 Response to Non-Final Office Action.
 U.S. Appl. No. 09/957,526, Jun. 23, 2003 Non-Final Office Action.
 U.S. Appl. No. 10/010,212, Mar. 6, 2006 Issue Fee payment.
 U.S. Appl. No. 10/010,212, Feb. 9, 2006 Notice of Allowance.
 U.S. Appl. No. 10/010,212, Dec. 27, 2005 Response to Final Office Action.

U.S. Appl. No. 10/010,212, Oct. 19, 2005 Final Office Action.
 U.S. Appl. No. 10/010,212, Aug. 4, 2005 Response to Non-Final Office Action.
 U.S. Appl. No. 10/010,212, May 6, 2005 Non-Final Office Action.
 U.S. Appl. No. 10/010,212, Feb. 4, 2005 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 10/010,212, Dec. 2, 2004 Final Office Action.
 U.S. Appl. No. 10/010,212, Aug. 9, 2004 Response to Non-Final Office Action.
 U.S. Appl. No. 10/010,212, Jun. 16, 2004 Non-Final Office Action.
 U.S. Appl. No. 10/010,212, Mar. 22, 2004 Response to Non-Final Office Action.
 U.S. Appl. No. 10/010,212, Dec. 31, 2003 Non-Final Office Action.
 U.S. Appl. No. 10/010,212, Oct. 14, 2003 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 10/010,212, Jul. 7, 2003 Final Office Action.
 U.S. Appl. No. 10/010,212, Apr. 18, 2003 Response to Non-Final Office Action.
 U.S. Appl. No. 10/010,212, Jan. 15, 2003 Non-Final Office Action.
 U.S. Appl. No. 10/010,212, Dec. 17, 2002 Response to Restriction Requirement.
 U.S. Appl. No. 10/010,212, Nov. 25, 2002 Restriction Requirement.
 U.S. Appl. No. 10/392,697, Aug. 22, 2007 Issue Fee payment.
 U.S. Appl. No. 10/392,697, May 31, 2007 Notice of Allowance.
 U.S. Appl. No. 10/392,697, Feb. 26, 2007 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 10/392,697, Jan. 5, 2007 Final Office Action.
 U.S. Appl. No. 10/392,697, Sep. 29, 2006 Response to Non-Final Office Action.
 U.S. Appl. No. 10/392,697, Jul. 13, 2006 Non-Final Office Action.
 U.S. Appl. No. 10/392,697, May 1, 2006 Response to Restriction Requirement.
 U.S. Appl. No. 10/392,697, Mar. 27, 2006 Restriction Requirement.
 U.S. Appl. No. 11/038,971, May 29, 2009 Issue Fee payment.
 U.S. Appl. No. 11/038,971, Mar. 13, 2009 Notice of Allowance.
 U.S. Appl. No. 11/038,971, Sep. 19, 2008 Response to Non-Final Office Action.
 U.S. Appl. No. 11/038,971, Jul. 29, 2008 Non-Final Office Action.
 U.S. Appl. No. 11/038,971, Feb. 28, 2008 Response to Non-Final Office Action.
 U.S. Appl. No. 11/038,971, Nov. 28, 2007 Non-Final Office Action.
 U.S. Appl. No. 11/038,971, Sep. 18, 2007 Response to Non-Final Office Action.
 U.S. Appl. No. 11/038,971, Jun. 28, 2007 Non-Final Office Action.
 U.S. Appl. No. 11/038,971, Apr. 12, 2007 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 11/038,971, Feb. 16, 2007 Final Office Action.
 U.S. Appl. No. 11/038,971, Nov. 13, 2006 Response to Non-Final Office Action.
 U.S. Appl. No. 11/038,971, Sep. 21, 2006 Non-Final Office Action.
 U.S. Appl. No. 11/196,134, Dec. 29, 2009 Issue Fee payment.
 U.S. Appl. No. 11/196,134, Sep. 30, 2009 Notice of Allowance.
 U.S. Appl. No. 11/196,134, Sep. 10, 2009 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 11/196,134, Jun. 10, 2009 Final Office Action.
 U.S. Appl. No. 11/196,134, Mar. 24, 2009 Response to Non-Final Office Action.
 U.S. Appl. No. 11/196,134, Dec. 24, 2008 Non-Final Office Action.
 U.S. Appl. No. 11/480,143, Feb. 3, 2011 Issue Fee payment.
 U.S. Appl. No. 11/480,143, Nov. 18, 2010 Notice of Allowance.
 U.S. Appl. No. 11/480,143, Aug. 23, 2010 Response to Non-Final Office Action.
 U.S. Appl. No. 11/480,143, Apr. 22, 2010 Non-Final Office Action.
 U.S. Appl. No. 11/480,143, Feb. 18, 2010 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 11/480,143, Feb. 4, 2010 Advisory Action.
 U.S. Appl. No. 11/480,143, Jan. 15, 2010 Response to Final Office Action.
 U.S. Appl. No. 11/480,143, Aug. 18, 2009 Final Office Action.
 U.S. Appl. No. 11/480,143, May 27, 2009 Response to Non-Final Office Action.
 U.S. Appl. No. 11/480,143, Jan. 27, 2009 Non-Final Office Action.

(56)

References Cited**OTHER PUBLICATIONS**

U.S. Appl. No. 11/480,143, Oct. 28, 2008 Response to Restriction Requirement.
 U.S. Appl. No. 11/480,143, Oct. 17, 2008 Restriction Requirement.
 U.S. Appl. No. 11/763,623, Jan. 29, 2013 Issue Fee Payment.
 U.S. Appl. No. 11/763,623, Oct. 29, 2012 Notice of Allowance.
 U.S. Appl. No. 11/763,623, Oct. 17, 2012 Applicant Initiated Interview Summary.
 U.S. Appl. No. 11/763,623, Oct. 21, 2010 Examiner Interview Summary.
 U.S. Appl. No. 11/763,623, Aug. 24, 2010 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 11/763,623, May 24, 2010 Notice of Appeal.
 U.S. Appl. No. 11/763,623, Feb. 23, 2010 Final Office Action.
 U.S. Appl. No. 11/763,623, Jan. 15, 2010 Response to Non-Final Office Action.
 U.S. Appl. No. 11/763,623, Oct. 15, 2009 Non-Final Office Action.
 U.S. Appl. No. 11/763,623, Jul. 20, 2009 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 11/763,623, Mar. 20, 2009 Final Office Action.
 U.S. Appl. No. 11/763,623, Mar. 3, 2009 Response to Non-Final Office Action.
 U.S. Appl. No. 11/763,623, Dec. 3, 2008 Non-Final Office Action.
 U.S. Appl. No. 11/763,623, Oct. 2, 2008 Response to Restriction Requirement.
 U.S. Appl. No. 11/763,623, Sep. 25, 2008 Restriction Requirement.
 U.S. Appl. No. 11/844,117, Aug. 2, 2011 Issue Fee payment.
 U.S. Appl. No. 11/844,117, Jun. 15, 2011 Notice of Allowance.
 U.S. Appl. No. 11/844,117, Mar. 23, 2011 Response to Non-Final Office Action.
 U.S. Appl. No. 11/844,117, Nov. 23, 2010 Non-Final Office Action.
 U.S. Appl. No. 11/844,117, Nov. 17, 2010 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 11/844,117, Aug. 17, 2010 Final Office Action.
 U.S. Appl. No. 11/844,117, Jun. 30, 2010 Response to Non-Compliant.
 U.S. Appl. No. 11/844,117, Jun. 23, 2010 Notice of Non-Compliant.
 U.S. Appl. No. 11/844,117, Jun. 17, 2010 Response to Non-Final Office Action.
 U.S. Appl. No. 11/844,117, Mar. 17, 2010 Non-Final Office Action.
 U.S. Appl. No. 11/844,117, Jan. 5, 2010 Response to Restriction Requirement.
 U.S. Appl. No. 11/844,117, Oct. 13, 2009 Restriction Requirement.
 U.S. Appl. No. 11/958,106, May 21, 2013 Certificate of Correction.
 U.S. Appl. No. 11/958,106, Feb. 20, 2013 Issue Fee payment.
 U.S. Appl. No. 11/958,106, Nov. 20, 2012 Notice of Allowance.
 U.S. Appl. No. 11/958,106, Oct. 23, 2012 Response to Non-Final Office Action.
 U.S. Appl. No. 11/958,106, Aug. 1, 2012 Non-Final Office Action.
 U.S. Appl. No. 11/958,106, May 29, 2012 Response to Non-Final Office Action.
 U.S. Appl. No. 11/958,106, May 17, 2012 Notice of Non-Compliant.
 U.S. Appl. No. 11/958,106, May 7, 2012 Response to Non-Final Office Action.
 U.S. Appl. No. 11/958,106, Jan. 6, 2012 Non-Final Office Action.
 U.S. Appl. No. 11/958,106, Jun. 17, 2010 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 11/958,106, Mar. 17, 2010 Final Office Action.
 U.S. Appl. No. 11/958,106, Jan. 8, 2010 Response to Non-Final Office Action.
 U.S. Appl. No. 11/958,106, Jul. 8, 2009 Non-Final Office Action.
 U.S. Appl. No. 12/324,425, Oct. 31, 2011 Amendment after Notice of Allowance.
 U.S. Appl. No. 12/324,425, Sep. 22, 2011 Issue Fee payment.
 U.S. Appl. No. 12/324,425, Aug. 31, 2011 Notice of Allowance.
 U.S. Appl. No. 12/324,425, Jun. 6, 2011 Response to Non-Final Office Action.
 U.S. Appl. No. 12/324,425, Mar. 4, 2011 Non-Final Office Action.
 U.S. Appl. No. 12/477,695, Jan. 21, 2016 Final Office Action.

U.S. Appl. No. 12/477,695, Oct. 1, 2015 Response to Non-Final Office Action.
 U.S. Appl. No. 12/477,695, Jul. 1, 2015 Non-Final Office Action.
 U.S. Appl. No. 12/477,695, May 16, 2014 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 12/477,695, Apr. 10, 2014 Applicant Initiated Interview Summary.
 U.S. Appl. No. 12/477,695, Mar. 17, 2014 Response after Final Action.
 U.S. Appl. No. 12/477,695, Jan. 16, 2014 Final Office Action.
 U.S. Appl. No. 12/477,695, Jan. 15, 2013 Amendment and Request for Continued Examination (RCE).
 U.S. Appl. No. 12/477,695, Oct. 24, 2012 Advisory Action.
 U.S. Appl. No. 12/477,695, Oct. 11, 2012 Response to Final Office Action.
 U.S. Appl. No. 12/477,695, Aug. 15, 2012 Final Office Action.
 U.S. Appl. No. 12/477,695, Apr. 16, 2012 Response to Non-Final Office Action.
 U.S. Appl. No. 12/477,695, Dec. 16, 2011 Non-Final Office Action.
 U.S. Appl. No. 12/477,695, Sep. 20, 2013 Response to Non-Final Office Action.
 U.S. Appl. No. 12/477,695, Jun. 20, 2013 Non-Final Office Action.
 U.S. Appl. No. 12/478,929, Apr. 18, 2013 Issue Fee payment.
 U.S. Appl. No. 12/478,929, Jan. 18, 2013 Notice of Allowance.
 U.S. Appl. No. 12/478,929, Sep. 24, 2012 Response to Non-Final Office Action.
 U.S. Appl. No. 12/478,929, Jun. 22, 2012 Non-Final Office Action.
 U.S. Appl. No. 12/478,929, Jul. 18, 2011 Request for Continued Examination (RCE).
 U.S. Appl. No. 12/478,929, Jul. 13, 2011 Advisory Action.
 U.S. Appl. No. 12/478,929, Jun. 6, 2011 Response to Final Office Action.
 U.S. Appl. No. 12/478,929, Mar. 4, 2011 Final Office Action.
 U.S. Appl. No. 12/478,929, Dec. 9, 2010 Response to Non-Final Office Action.
 U.S. Appl. No. 12/478,929, Jul. 9, 2010 Non-Final Office Action.
 U.S. Appl. No. 12/479,700, Sep. 22, 2011 Issue Fee payment.
 U.S. Appl. No. 12/479,700, Aug. 22, 2011 Notice of Allowance.
 U.S. Appl. No. 12/479,700, May 20, 2011 Response to Interview Summary.
 U.S. Appl. No. 12/479,700, May 13, 2011 Examiner Interview Summary.
 U.S. Appl. No. 12/479,700, Apr. 27, 2011 Response to Non-Final Office Action.
 U.S. Appl. No. 12/479,700, Oct. 27, 2010 Non-Final Office Action.
 U.S. Appl. No. 12/479,700, Oct. 14, 2010 Response to Restriction Requirement.
 U.S. Appl. No. 12/479,700, Oct. 4, 2010 Restriction Requirement.
 U.S. Appl. No. 12/687,265, Oct. 14, 2010 Issue Fee payment.
 U.S. Appl. No. 12/687,265, Aug. 5, 2010 Notice of Allowance.
 U.S. Appl. No. 13/224,917, Mar. 25, 2015 Issue Fee payment.
 U.S. Appl. No. 13/224,917, Mar. 2, 2015 Notice of Allowance.
 U.S. Appl. No. 13/224,917, Dec. 10, 2014 Response to Non-Final Office Action.
 U.S. Appl. No. 13/224,917, Oct. 12, 2012 Non-Final Office Action.
 U.S. Appl. No. 13/224,917, Sep. 11, 2014 Non-Final Office Action.
 U.S. Appl. No. 13/224,917, Dec. 13, 2013 Response to Non-Final Office Action.
 U.S. Appl. No. 13/224,917, Sep. 12, 2013 Non-Final Office Action.
 U.S. Appl. No. 13/224,917, Aug. 23, 2013 Amendment and Request for Continued.
 U.S. Appl. No. 13/224,917, May 28, 2013 Final Office Action.
 U.S. Appl. No. 13/224,917, Jan. 14, 2013 Response to Non-Final Office Action.
 U.S. Appl. No. 13/240,453, Nov. 19, 2013 Issue Fee payment.
 U.S. Appl. No. 13/240,453, Aug. 20, 2013 Notice of Allowance.
 U.S. Appl. No. 13/240,453, Apr. 30, 2013 Response to Non-Final Office Action.
 U.S. Appl. No. 13/240,453, Apr. 17, 2013 Applicant Initiated Interview Summary.
 U.S. Appl. No. 13/240,453, Dec. 5, 2012 Non-Final Office Action.
 U.S. Appl. No. 13/240,453, Nov. 1, 2012 Response to Restriction Requirement.

(56)

References Cited

OTHER PUBLICATIONS

U.S. Appl. No. 13/240,453, Oct. 2, 2012 Restriction Requirement.
 U.S. Appl. No. 13/398,178, Jan. 25, 2013 Issue Fee Payment.
 U.S. Appl. No. 13/398,178, Oct. 25, 2012 Notice of Allowance.
 U.S. Appl. No. 13/398,178, Oct. 16, 2012 Preliminary Amendment.
 U.S. Appl. No. 13/562,810, Jan. 9, 2014 Issue Fee payment.
 U.S. Appl. No. 13/562,810, Nov. 6, 2013 Notice of Allowance.
 U.S. Appl. No. 13/562,810, Oct. 8, 2013 Response to Non-Final Office Action.
 U.S. Appl. No. 13/562,810, Jul. 8, 2013 Non-Final Office Action.
 U.S. Appl. No. 13/775,659, May 12, 2015 Issue Fee payment.
 U.S. Appl. No. 13/775,659, Feb. 17, 2015 Notice of Allowance.
 U.S. Appl. No. 13/775,659, Jan. 26, 2015 Response to Non-Final Office Action.
 U.S. Appl. No. 13/775,659, Oct. 24, 2014 Non-Final Office Action.
 U.S. Appl. No. 13/775,699, Mar. 31, 2014 Issue Fee payment.
 U.S. Appl. No. 13/775,699, Dec. 31, 2013 Notice of Allowance.
 U.S. Appl. No. 13/775,699, Oct. 28, 2013 Response to Restriction Requirement.
 U.S. Appl. No. 13/775,699, Sep. 27, 2013 Restriction Requirement.
 U.S. Appl. No. 14/180,550, Nov. 17, 2015 Issue Fee payment.
 U.S. Appl. No. 14/180,550, Aug. 17, 2015 Notice of Allowance.

U.S. Appl. No. 14/180,550, Apr. 13, 2015 Response to Non-Final Office Action.
 U.S. Appl. No. 14/180,550, Jan. 13, 2015 Non-Final Office Action.
 U.S. Appl. No. 14/230,581, Nov. 5, 2015 Issue Fee payment.
 U.S. Appl. No. 14/230,581, Aug. 5, 2015 Notice of Allowance.
 Cordis' Product Brochure; The Journey Inspires the Design, Aqua T3, Dec. 2002.
 Etherington & Roberts Dictionary, <http://Palimpsest.stanford.edu/don/dt/dt1549.html>. Accessed on Jan. 9, 2003.
http://www.zeusinc.com/peek_resin.asp. Accessed on Jun. 10, 2004.
 International Search Report for PCT/US2007/071873, dated Apr. 14, 2008.
 International Search Report for PCT/US2008/086270, dated Jun. 3, 2009.
 International Search Report for PCT/US2010/037313, dated Apr. 28, 2011.
 Polymers: Structure and Properties, C.A. Daniels, Ph.D., P.E.; Technomic Publishing Co., Inc. (Date is unavailable).
 The Manufacturing Process Section of the Phelps Dodge High Performance Conductors Brochure, a Primer on Polyimide Tubing, pp. 1. (Date is unavailable).
www.sigmaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers.pdf (Date is unavailable).

* cited by examiner

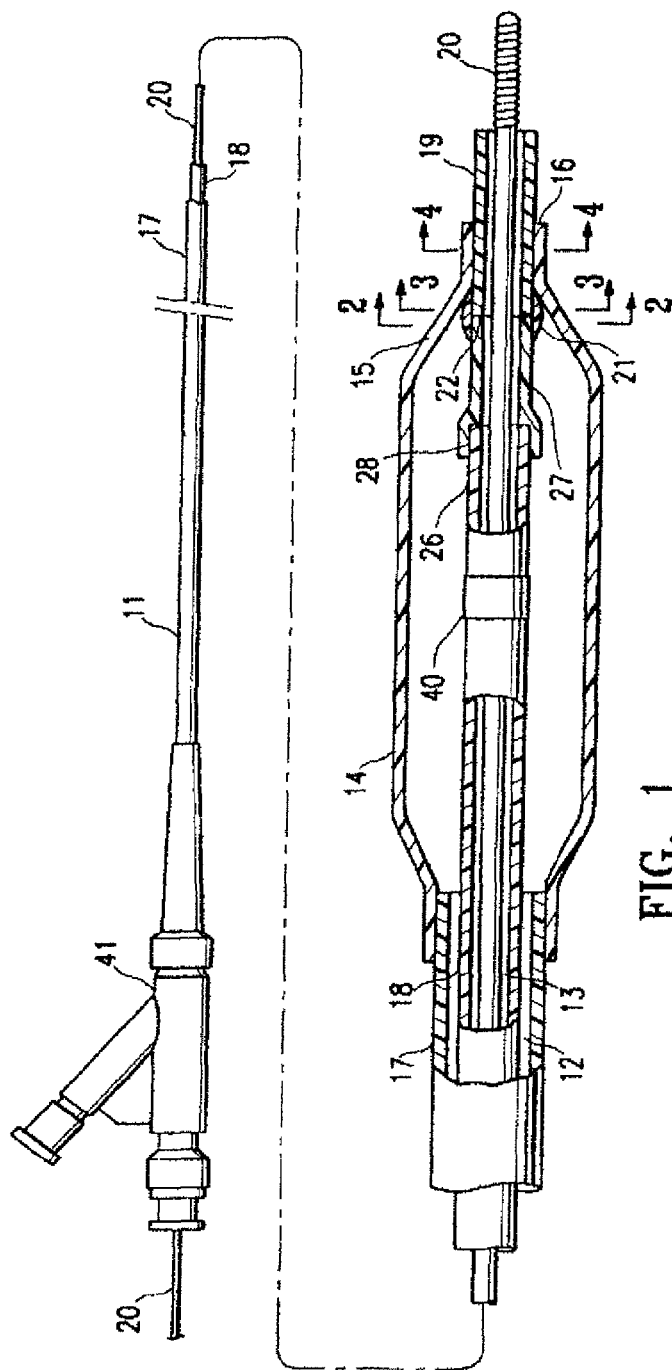


FIG. 1

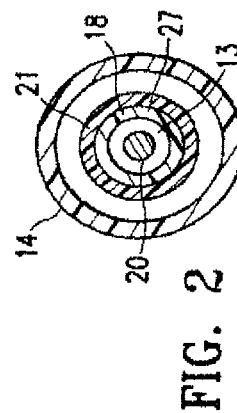


FIG. 2

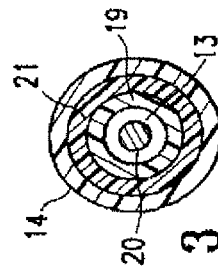


FIG. 3

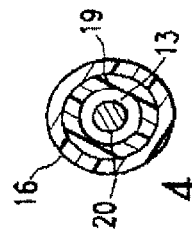


FIG. 4

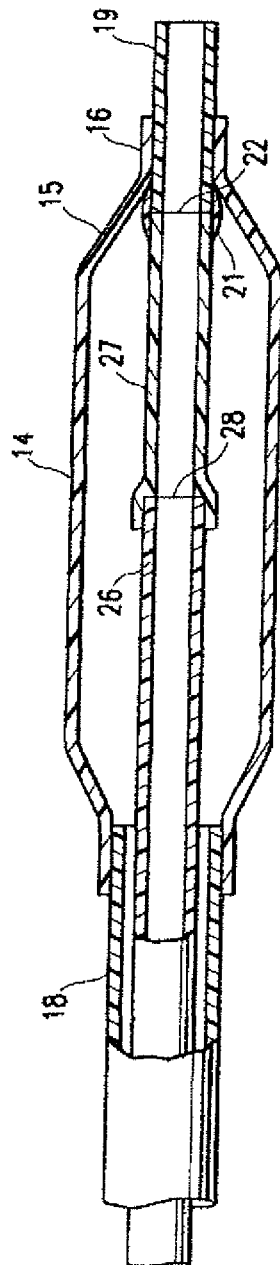


FIG. 5

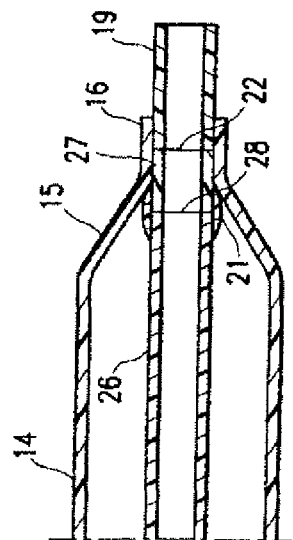


FIG. 6

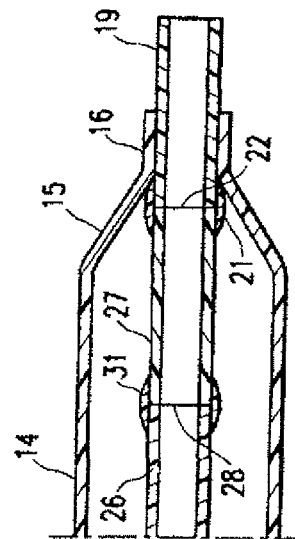


FIG. 7

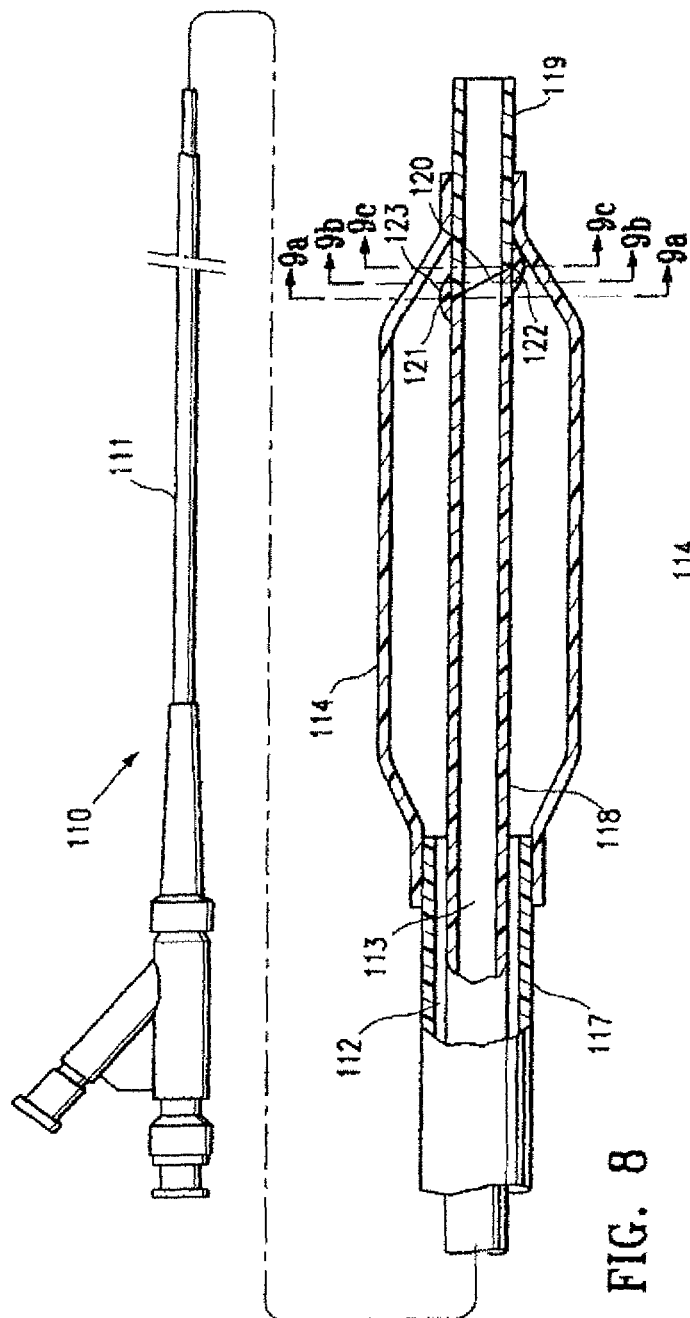


FIG. 8

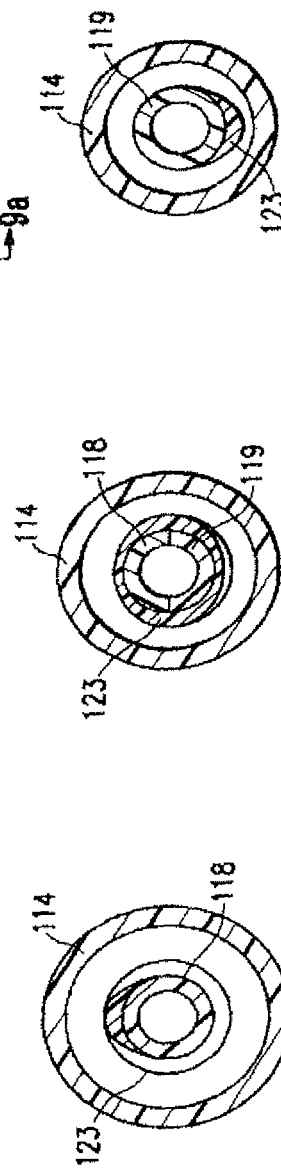


FIG. 9a

FIG. 9b

FIG. 9c

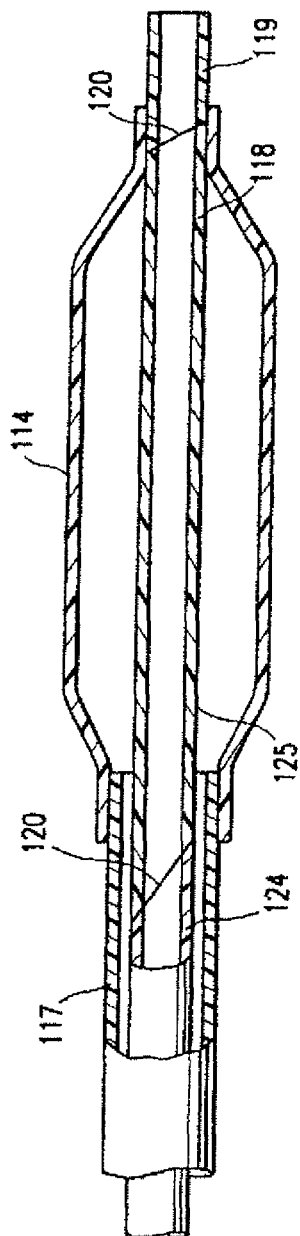


FIG. 10

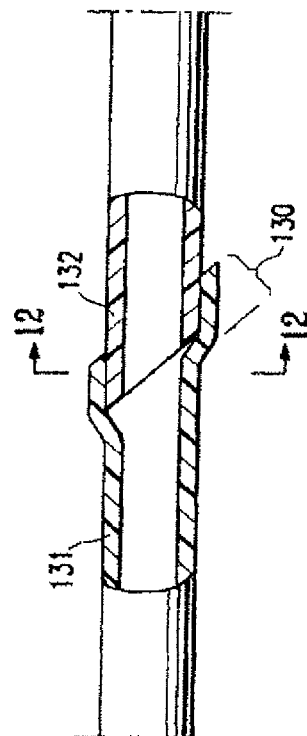


FIG. 11



FIG. 12

CATHETER HAVING TRANSITIONING SHAFT SEGMENTS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/180,550, entitled "Catheter Having Transitioning Shaft Segments" and filed Feb. 14, 2014; which is a continuation of U.S. patent application Ser. No. 13/562,810, entitled "Catheter Having Transitioning Shaft Segments" and filed Jul. 31, 2012, which issued as U.S. Pat. No. 8,657,782 on Feb. 25, 2014; which is a continuation of U.S. patent application Ser. No. 11/958,106, entitled "Catheter Having Transitioning Shaft Segments" and filed Dec. 17, 2007, which issued as U.S. Pat. No. 8,403,885 on Mar. 26, 2013, the contents of each of which is hereby incorporated by reference in its entirety herein.

BACKGROUND OF THE INVENTION

This invention generally relates to catheters, and particularly intravascular catheters for use in percutaneous transluminal coronary angioplasty (PTCA) or for the delivery of stents.

In percutaneous transluminal coronary angioplasty (PTCA) procedures, a guiding catheter is advanced in the patient's vasculature until the distal tip of the guiding catheter is seated in the ostium of a desired coronary artery. A guidewire is first advanced out of the distal end of the guiding catheter into the patient's coronary artery until the distal end of the guidewire crosses a lesion to be dilated. A dilatation catheter, having an inflatable balloon on the distal portion thereof, is advanced into the patient's coronary anatomy over the previously introduced guidewire until the balloon of the dilatation catheter is properly positioned across the lesion. Once properly positioned, the dilatation balloon is inflated with inflation fluid one or more times to a predetermined size at relatively high pressures so that the stenosis is compressed against the arterial wall and the wall expanded to open up the vascular passageway. Generally, the inflated diameter of the balloon is approximately the same diameter as the native diameter of the body lumen being dilated so as to complete the dilatation but not over expand the artery wall. After the balloon is finally deflated, blood resumes through the dilated artery and the dilatation catheter and the guidewire can be removed there from.

In such angioplasty procedures, there may be restenosis of the artery, i.e., reformation of the arterial blockage, which necessitates either another angioplasty procedure, or some other method of repairing or strengthening the dilated area. To reduce the restenosis rate of angioplasty alone and to strengthen the dilated area, physicians now normally implant an intravascular prosthesis, generally called a stent, inside the artery at the site of the lesion. Stents may also be used to repair vessels having an intimal flap or dissection or to generally strengthen a weakened section of a vessel or to maintain its patency. Stents are usually delivered to a desired location within a coronary artery in a contracted condition on a balloon of a catheter which is similar in many respects to a balloon angioplasty catheter, and expanded within the patient's artery to a larger diameter by expansion of the balloon. The balloon is deflated to remove the catheter and the stent left in place within the artery at the site of the dilated lesion. For details of stents, see for example, U.S. Pat. No. 5,507,768 (Lau, et al.) and U.S. Pat. No. 5,458,615 (Klemm, et al.), which are incorporated herein by reference.

An essential step in effectively performing a PTCA procedure is properly positioning the balloon catheter at a desired location within the coronary artery. To properly position the balloon at the stenosed region, the catheter must have good pushability (i.e., ability to transmit force along the length of the catheter), and good trackability and flexibility, to be readily advanceable within the tortuous anatomy of the patient's vasculature. Conventional balloon catheters for intravascular procedures, such as angioplasty and stent delivery, frequently have a relatively stiff proximal shaft section to facilitate advancement of the catheter within the patient's body lumen and a relatively flexible distal shaft section to facilitate passage through tortuous anatomy such as distal coronary and neurological arteries without damage to the vessel wall. These flexibility transitions can be achieved by a number of methods, including bonding two or more segments of different flexibility together to form the shaft. However, such transition bonds must be sufficiently strong to withstand the pulling and pushing forces on the shaft during use. One difficulty has been providing a flexibility transition which improves catheter maneuverability, yet with a sufficiently strong transition bond, especially at the transition between the distal end of the shaft inner tubular member (extending through the balloon interior) and a soft distal tip member formed of a relatively soft material to provide an atraumatic distal leading end for the catheter. If the tip pull strength is low, the soft distal tip member could tear or become detached during use, which can result in serious harm or death to the patient. Moreover, the need for high tip pull strength often competes with the desire for a low tip crossing profile, i.e., efforts to increase the strength of the bond between the soft distal tip member and the balloon and/or inner tubular member often result in an increased distal seal profile. Accordingly, it would be a significant advance to provide a catheter having an improved flexibility transition with a low profile.

SUMMARY OF THE INVENTION

The invention is directed to a catheter having shaft segments which are joined together by a strong bond providing a low profile shaft section with a flexibility transition and/or a compositional transition.

In a presently preferred embodiment, the catheter is a balloon catheter with a balloon on a distal shaft section, having an interior in fluid communication with the at least one lumen of the catheter shaft. A balloon catheter of the invention generally comprises an elongated shaft having a proximal shaft section, a distal shaft section, an inflation lumen extending within the proximal and distal shaft sections, and a guidewire receiving lumen extending at least within the distal shaft section, and an inflatable balloon on the distal shaft section with an interior in fluid communication with the inflation lumen. The balloon typically has a proximal skirt section and a distal skirt section sealingly secured to the shaft, and an inflatable working length and proximal and distal cone sections defining the inflatable interior of the balloon located between the skirt sections of the balloon. In a presently preferred embodiment, the shaft comprises an outer tubular member defining the inflation lumen, and an inner tubular member defining at least a portion of the guidewire receiving lumen. However, a variety of suitable shaft designs may be used including a single-lumen shaft, or eccentric multi-lumen type shafts such as a catheter having the balloon proximal skirt section bonded to the distal end of a dual-lumen type shaft, and the balloon distal skirt section bonded to the distal end of an

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inner tubular member extending from the distal end of the dual lumen shaft. The balloon catheter of the invention may comprise a variety of suitable balloon catheters, including coronary and peripheral dilatation catheters, stent delivery catheters, drug delivery catheters, and the like.

In one embodiment, a balloon catheter of the invention has a distal tip member and a coupling band member surrounding a junction of the shaft inner tubular member, and has a gradual change in bending stiffness along a distal end section of the shaft which extends distally from a location within the balloon interior. Specifically, the balloon catheter has a distal tip member which is secured to a distal end of the inner tubular member (i.e., the portion of the shaft extending in the balloon interior) to define a distal end section of the shaft lumen, and a distal coupling band member on an outer surface of the inner tubular member surrounding a junction of the inner tubular member, having a distal end which abuts the inner surface of the balloon at a distal end of the distal cone section of the balloon. The distal coupling band member preferably abuts but does not bond to the interior surface of the distal cone section of the balloon, and consequently preferably improves tip pull strength without damaging or otherwise weakening the integrity of the balloon wall. The coupling band member preferably has a low profile, to minimize the shaft profile therealong. In one embodiment, the tip member is a soft distal tip formed at least in part of a softer polymeric material (e.g., having a lower Shore durometer hardness) than the distal end of the shaft inner tubular member.

In another embodiment, a catheter of the invention has shaft segments joined together by a diagonal seam, and generally comprises an elongated shaft having a proximal end, a distal end, a proximal tubular member, and a distal tubular member which has a diagonally extending proximal end bonded to a diagonally extending distal end of the proximal tubular member, such that the bond between the ends extends from a first side of the shaft diagonally to an opposite side of the shaft (i.e., diagonally across the lumen defined by the tubular members) to form a diagonal seam. The diagonal seam can be used to join a soft tip member to the shaft inner member, or additionally or alternatively to join more proximal shaft segments together.

Although discussed primarily in terms of a junction between different stiffness tubular members providing a flexibility transition, it should be understood that the junctions of the invention can additionally or alternatively provide a change in the composition of the shaft in order to change different shaft characteristics such as bondability, lubricity, radiopacity, color, and the like.

A catheter of the invention has an improved transition, such as a flexibility transition along a length of the catheter shaft which preferably provides improved trackability. These and other advantages of the invention will become more apparent from the following detailed description and accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view, partially in section, of a balloon catheter embodying features of the invention, having a distal coupling band member surrounding a junction between an inner tubular member and a distal tip member.

FIGS. 2-4 are transverse cross sectional views of the catheter of FIG. 1, taken along lines 2-2, 3-3 and 4-4, respectively.

FIG. 5 illustrates an alternative embodiment of the catheter of FIG. 1, in which the inner tubular member includes

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a proximal member and a distal member joined together at about the center of the working length of the balloon.

FIG. 6 illustrates an alternative embodiment of the catheter of FIG. 1, in which the distal coupling band member surrounds a junction between the proximal and distal members of the inner tubular member.

FIG. 7 illustrates an alternative embodiment of the catheter of FIG. 1, in which the catheter includes a proximal coupling band member surrounding the bond between the proximal and distal members of the inner tubular member.

FIG. 8 is an elevational view, partially in section, of an alternative catheter embodying features of the invention, having shaft segments joined by a diagonal seam and a diagonally extending coupling band member.

FIGS. 9a, 9b, and 9c are transverse cross sections of FIG. 8, taken through lines 9a-9a, 9b-9b, and 9c-9c, respectively.

FIG. 10 illustrates an alternative embodiment of the invention, having a first diagonal seam, and a second diagonal seam between two shaft segments located proximal to the soft tip member of the catheter.

FIG. 11 illustrates an alternative embodiment of the invention, having a diagonal seam formed by shaft segments with overlapping diagonal ends.

FIG. 12 is a transverse cross section of FIG. 11, taken through line 12-12.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates an elevational view, partially in section, of a balloon catheter 10 embodying features of the invention, generally comprising an elongated shaft 11 having a proximal end, a distal end, an inflation lumen 12, a guidewire receiving lumen 13, and a balloon 14 on a distal shaft section having an inflatable working length between an inflatable proximal cone section and an inflatable distal cone section 15, and a proximal skirt section and distal skirt section 16 sealingly secured to the shaft, such that an interior of the balloon is in fluid communication with the inflation lumen 12. In the illustrated embodiment the shaft 11 comprises an outer tubular member 17 with the inflation lumen 12 therein, and an inner tubular member 18 with the guidewire lumen 13 therein, and a distal tip member 19 is secured to a distal end of the inner tubular member 18 to define a distal end section of the guidewire lumen. A radiopaque marker band 40 of metal or radiopaque loaded polymer is on the inner tubular member at about the center of the working length of the balloon, although radiopaque markers can be provided at a variety of locations including at the ends of the working length section. An adapter 41 on the distal end of the shaft has a port configured for connecting to a fluid delivery source (not shown) for inflating/deflating the balloon 14. The catheter 10 can be advanced within a patient's vasculature to position the balloon 14 at a desired location with the balloon in a low profile deflated configuration, and the balloon inflated to perform a medical procedure one or more times, and the balloon deflated for removal from the patient. FIG. 1 illustrates the balloon in an inflated configuration, with a guidewire 20 slidably disposed in the guidewire lumen 13.

In the embodiment of FIG. 1, the inner tubular member 18 comprises a proximal member 26, and a distal member 27 which has a proximal end bonded to a distal end of the proximal member 26, and which forms the distal end of the inner tubular member bonded to the distal tip member 19. Typically, the distal member 27 of the inner tubular member is more flexible than the proximal member 26, to improve

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the ability of the catheter to track along the guidewire **20** and be advanced within a patient's tortuous anatomy. The distal tip member **19** is typically formed of a relatively soft polymeric material providing an atraumatic distal leading end, and in one embodiment, is formed at least in part of a softer polymeric material than the distal end section of the inner tubular member immediately proximally adjacent to the soft distal tip member **19**. The soft distal tip member **19** can be formed of a variety of suitable polymeric materials, although at least the outer surface is preferably fusion bond compatible with the material of the balloon **14**. The relatively low Shore durometer hardness of the soft distal tip material is typically about 35 to about 70 D. In the embodiment of FIG. 1, a proximal end of the distal tip member **19** is located in the balloon inflatable interior proximal to the distal skirt section **16**, and the distal skirt section **16** is sealingly secured to an outer surface of (only) the distal tip member **19**.

A distal coupling band member **21** on an outer surface of the inner tubular member **18** surrounds a junction **22** of the inner tubular member **18**, and has a distal end which abuts the inner surface of the balloon **14** at a distal end of the distal cone section **15**. The junction surrounded by the distal coupling band member **21** is between the distal end of the inner tubular member **18** and the proximal end of the distal tip member **19**. Specifically, the distal tip member **19** and the distal member **27** of the inner tubular member **18** are bonded end-to-end, with the distal coupling band member surrounding the abutting ends of the tubular members. The distal coupling band member **21** is formed of a polymeric material, and has an inner surface bonded to the outer surfaces of the inner tubular member **18** and distal tip member **19** across the junction **22**, to strengthen the junction. The distal coupling band member is preferably fusion bonded to the outer surfaces of the shaft members **18**, **19**. Additionally, at least a layer of the inner tubular member **18** fusion bonds to the abutting end of the distal tip **19** to form the junction **22**. Although adhesive bonding is possible it is much less preferred due at least in part to manufacturing complications. FIGS. 2-4 are transverse cross sectional views of the catheter of FIG. 1, taken along lines 2-2, 3-3 and 4-4, respectively.

The distal coupling band member **21** is not bonded to the balloon **14**. Thus, the outer end surface of the distal coupling band member **21** that abuts the inner surface of the distal cone of the balloon is not bonded to said inner surface of the balloon. Preferably, to prevent such bonding from occurring, the distal cone of the balloon is cooled during heat fusion bonding of the distal skirt section of the balloon to the underlying section of the distal tip member **19**, for example by directing a cooling fluid (e.g., air stream) at the distal cone. The coupling band member **21** preferably has a low profile, and specifically, in one embodiment is about 0.03 to about 0.07 mm thick. However, the coupling band member **21** is configured to provide a moderate profile increase sufficient to prevent pullout to improve tip pull strength, and is thus unlike conventional thin metal marker bands commonly embedded in the shaft to minimize any local profile increase. Although the coupling band member **21** is thin, it preferably does not extend under the distal skirt section **16** of the balloon. Prior to bonding, the distal skirt section **16** of the balloon has an inner diameter closely matched to the outer diameter of the section of the shaft (e.g., the distal tip member **19**) to be bonded thereto, such that the resulting distal skirt section seal has a low profile. During assembly, the distal tip member **19** is slid distally through the distal skirt section until the distal coupling band member, prefer-

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ably acting as a stop, abuts the inner surface of the distal cone. With the distal tip member **19** thus in position under the distal skirt **16**, the bond between the distal skirt **16** and distal tip **19** is formed. In the resulting finished catheter, the distal coupling band member increases the tip pull strength (i.e., the ability of the catheter at the distal tip **19** to withstand pushing and pulling forces).

The polymeric material of the distal coupling band member **21** can melt and flow during bonding to the shaft **11**. However, the bulk of the material of the distal coupling band member **21** must remain over the inner member junction **22** for functioning as the required coupler, and for preferably acting as a stop which abuts the inner surface of the inflatable cone **15** of the balloon **14**. Thus, the distal coupling band member **21** preferably does not extend under the distal skirt section **16** of the balloon **14**, or otherwise does not substantially increase the profile at the distal skirt **16** (e.g., by no more than 0.0005 to about 0.002 inches, or about 2 to about 10% of the outer diameter at the distal skirt **16**).

The distal coupling band member **21** has a relatively short length configured to provide sufficient strengthening of the junction **22** while minimizing the length (to minimize any stiffness/profile disadvantageous effects), thus, in one embodiment the proximal end of the distal coupling band member **21** is located closer to the distal end of the distal cone section **15** than to a proximal end of the distal cone section **15** of the balloon **14**. However, depending on the size of the balloon, the proximal end of the distal coupling band member **21** could be anywhere along the length of the distal cone of the balloon. The distal coupling band member **21** length is typically about 1 to about 3 mm.

In the embodiment of FIG. 1, the inner tubular member proximal and distal member junction **28** is a lap joint at the distal end of the working length of the balloon. However, the inner member can have a variety of suitable configurations including being a single unitary tube, or multiple tubes joined by end-to-end joints or lap joints. FIG. 5 illustrates an alternative embodiment similar to the embodiment of FIG. 1 except that the inner tubular member proximal member **26** and distal member **27** are joined together at about the center of the working length of the balloon **14**.

In the embodiment of FIG. 1, the distal coupling band member **21** surrounds the junction **22** of the distal member **27** and the distal tip member **19**. FIG. 6 illustrates an alternative embodiment which is similar to the embodiment of FIG. 1 except that the distal coupling band member **21** surrounds a junction **28** between the proximal and distal members **26**, **27** of the inner tubular member **18**. In the embodiment illustrated in FIG. 6, the balloon distal skirt section **16** surrounds the junction **22** between the distal tip member **19** and the distal member **27**, although in an alternative embodiment (not shown), the junction **22** between the distal tip member **19** and distal member **27** is proximal to the balloon distal skirt section **16**, with a coupling band member surrounding one or both of the junctions **22**, **28**.

FIG. 7 illustrates an alternative embodiment similar to the catheter of FIG. 1 except that the catheter includes a proximal coupling band member **31** surrounding the bond **28** between the proximal and distal members **26**, **27** of the inner tubular member **18**. In the illustrated embodiment, the proximal coupling band member **31** is at the center of the working length of the balloon **14**, although the proximal coupling band member **31** and inner member junction **28** there under can be at a variety of suitable longitudinal locations along the shaft, typically within the inflatable interior of the balloon **14**. For example, in alternative

embodiments (not shown) the proximal coupling band member **31** and inner tubular member junction **28** there under are located at the distal end of the working length of the balloon **14** (at the proximal end of the distal cone section **15**), or along the distal cone section **15** of the balloon **14**.

In a presently preferred embodiment the coupling band members **21**, **31** are formed of a polyether block amide (PEBAX) copolymer. However, the coupling band members **21**, **31** can be formed of a variety of suitable polymeric materials, which are preferably fusion bond compatible with the outer layers of the underlying tubular members, and which include polyamides, polyurethanes, high density polyethylene (HDPE), ultrahigh molecular weight polyethylene (UHMWPE), and polyimide. In an embodiment in which the proximal coupling band member **31** is located at the working length of the balloon **14**, it is preferably a polymeric material loaded with radiopaque material, to function as a radiopaque marker band. The distal coupling band member **21** is preferably not radiopaque, due to its location.

FIG. **8** illustrates an alternative catheter **110** embodying features of the invention, having shaft segments joined by a diagonal seam **120** and a diagonally extending coupling band member **123** surrounding the diagonal seam. In the illustrated embodiment, the catheter **110** is a balloon catheter generally comprising an elongated shaft **111** having a proximal end, a distal end, an inflation lumen **112**, a guidewire receiving lumen **113**, and a balloon **114** on a distal shaft section having an interior in fluid communication with the inflation lumen **112**. In the embodiment of FIG. **8**, the shaft **111** comprises an outer tubular member **117** with the annular inflation lumen **112** therein, an inner tubular **118** with the guidewire lumen **113** therein, and a distal tip member **119** (e.g., a soft tip member) which is secured to a distal end of the inner tubular member **118** to thereby define a distal portion of the guidewire lumen **113** and which is formed at least in part of a softer polymeric material than the distal end of the inner tubular member **118**. Although illustrated in a balloon catheter **110**, it should be understood that the diagonal seam **120** of the invention can be used to join shaft segments of a variety of suitable catheters including stent and drug delivery catheters (with or without a balloon), and the like.

The distal tip member **119** has a diagonally extending proximal end bonded to a diagonally extending distal end of the inner tubular member **118**, such that the bond between the ends extends from a first side of the shaft diagonally to the opposite side of the shaft (i.e., diagonally across the guidewire lumen **113** defined by the tubular members **118**, **119**) to form diagonal seam **120**. Because the seam **120** is diagonal, the proximal end **121** of the seam is at the first side of the shaft while the distal end **122** of the seam is at the opposite side of the shaft, and portions of the inner tubular member **118** radially adjacent to the proximal end **121** of the seam **120** (i.e., in a transverse cross section in a plane perpendicular to the shaft axis taken through the proximal end **121**) are proximally spaced from longitudinally adjacent middle portions of the seam located between the ends **121**, **122** of the seam **120**. The diagonal seam **120** provides a gradual flexibility transition in which the material of the inner tubular member gradually gives way to the material of the soft distal tip member along the entire length of the bond (i.e., from the proximal end **121** to the distal end **122** of the bond). As a result, in contrast to a joint between tubular members with a straight cut end(s), the diagonal seam of the invention provides a less abrupt change in stiffness along the axial (longitudinal) direction. Additionally, the diagonal

seam results in a stronger junction than a straight cut butt, lap, or otherwise coupled seam of similar diameter, as discussed in more detail below.

In the embodiment of FIG. **8**, the diagonally extending ends are butt joined together (i.e., without overlapping the inner and outer surfaces of the tubular members **118**, **119**). The diagonal seam provides a strong bond. Specifically, unlike a conventional butt joint between straight ends, the diagonally extending ends provide a longer bond length and correspondingly larger bond cross-sectional area for bonding together. The longer bond length of the diagonal butt joint bond is particularly advantageous in an embodiment in which one or both of the tubular members **118**, **119** is a multilayered tubular member having a layer of material which is not readily bondable. For example, the inner tubular member **118** preferable has an outer layer of a material such as a polyamide which facilitates bonding to adjacent components, and an inner layer of a lubricious/low friction material such as HDPE which has a relatively low surface energy and which is not readily fusion or adhesively bonded to other polymeric materials such as polyamides commonly used to form soft tip members. Thus, the diagonal butt joint bond increases the surface area of the bondable outer layer material contributing to the bond, thereby providing a stronger bond to the soft distal tip member formed at least in part of a material compatible with the outer layer material of the inner tubular member.

In a method of forming the diagonal seam **120**, the ends of the inner tubular member **118** and distal tip member **119** are made to taper diagonally at the same angle, typically by cutting or otherwise mechanically removing material from the end of each tubular member **118**, **119**. The resulting diagonally extending surfaces are put together such that the inner and outer surfaces of the inner tubular member **118** are aligned with the inner and outer surfaces, respectively, of the distal tip member **119**. The mating surfaces are then bonded together to form the diagonal bonded seam **120**, typically by heat fusing by focusing a heat source on the mating surfaces to soften the polymeric materials and then allowing the heated materials to cool and solidify together. Alternatively, an adhesive can be provided between the mating surfaces, such that the resulting diagonal seam **120** is an adhesive bond. The terminology "bonded seam" should be understood to refer to a bond formed between two separately formed tubes, and not a bond which naturally results during formation thereof such as by coextrusion of a multilayered/multisectioned shaft. The tubular members are typically formed by hot melt extrusion, and thus the bonded seam is formed after extrusion of the tubular members. A mandrel is typically provided inside the tubular members **118**, **119** during bonding to support the luminal shape, and a heat shrink tube (not shown) is typically provided on the tubular members **118**, **119** at the location of the mating surfaces, to facilitate forcing the mating surfaces together during bonding, and which is removed and discarded after formation of the bond. The length of the resulting diagonal seam can vary depending on characteristics such as the location of the seam **120** along the length of the catheter, the nature of the tubular members bonded together thereby, and the desired characteristics of the transition formed thereby. The diagonal butt joint seam **120** located in the balloon interior or elsewhere along the length of the catheter generally has a length of about 0.5 mm to about 40 mm, more typically about 20 to about 30 mm.

The diagonal butt joint bond **120** does not increase the profile of the shaft. The outer surface of the inner tubular member **118** aligns with the outer surface of the soft tip

member 119 prior to the bonding. In contrast, if the inner tubular member 118 had a conventionally tapered distal end (i.e., which decreases the outer diameter of the tubular member by tapering uniformly around the entire circumference of the tubular member), the proximal end of the soft tip member would have to flare outwardly to bond by overlapping the tapered distal end, and thus would increase the profile of the shaft therealong. Moreover, compared to bonding to a conventionally tapered end, the diagonal ends facilitate forming a relatively long bond length because the diagonal seam 120 extends diagonally across the shaft lumen (e.g., guidewire lumen 113) from one side to the opposite side of the shaft 111.

As with the embodiment of FIG. 1, coupling band member 123 covers the seam between the inner tubular member 118 and the soft distal tip member 119. In the embodiment of FIG. 8, the coupling band member 123 extends diagonally, preferably at an angle corresponding to the diagonal butt joint seam 120. Specifically, the diagonally extending coupling band member 123 surrounds the diagonal seam 120 on an outer surface of the tubular members 118, 119, and has diagonal proximal and distal ends extending diagonally across the inner diameters of the tubular members 118, 119. The discussion above relating to the materials of the coupling band member of the embodiment of FIG. 1 applies to diagonal coupling band member 123. FIGS. 9a-9a, 9b-9b and 9c-9c illustrate transverse cross sections of the catheter of FIG. 8 taken along lines 9a-9a, 9b-9b, and 9c-9c, respectively. The diagonal coupling band member 123 extends fully around the circumference of the shaft 111, to reinforce the diagonal seam 120, but provides a more gradual change in stiffness and profile than a coupling band having straight end(s). In the illustrated embodiment, the distal end of the diagonal coupling band member 123 abuts the inner surface of the balloon at a distal end of the distal cone section. However, the location of the diagonal coupling band member 123 (and diagonal seam 120 there under) can vary.

Although the embodiment illustrated in FIG. 8 has the diagonal seam 120 between the inner tubular member and the distal tip in the balloon interior, it should be understood that the diagonal seam 120 can be used at any location along the length of the catheter 110 from the proximal to the distal end of the catheter, and including between segments of the outer tubular member 117 of the shaft 111 in addition to or as opposed to the inner tubular member 118. One embodiment has multiple flexibility transitions provided by multiple diagonal seams in accordance with the invention at different longitudinal locations along the shaft. FIG. 10 illustrates an alternative embodiment of the invention in which the shaft 111 has a first diagonal seam 120 which is between the inner tubular member 118 and tip member 119 and which is located under the distal skirt of the balloon 114, and a second diagonal seam 120 between two segments 124, 125 of the inner tubular member 118 located proximal to the soft tip member 119. In the embodiment of FIG. 10, the two diagonal seams 120 extend diagonally at different angles but toward the same side of the shaft (circumferential orientation). In alternative embodiments the seams 120 have the same angle and/or a different circumferential orientation. Although the distal diagonal seam 120 is illustrated in FIG. 10 with a relatively short length that is entirely under the balloon distal skirt section 16, in alternative embodiments the distal diagonal seam 120 has a longer length/more acute angle such that it extends from under the skirt 16 to a location proximal and/or distal of the balloon distal skirt section 16. For example, in one embodiment, the diagonal seam 120 located in part under the balloon distal skirt

section 16 has a proximal end 121 located at the proximal end of the cone section of the balloon (at the distal end of the working length of the balloon). As a result, in one embodiment, the length of a proximal end section of the distal tip from the proximal to the distal end of the diagonal seam is longer than the length of a distal section of the distal tip from the distal end of the diagonal seam to the distal end of the distal tip member 119.

FIG. 11 illustrates an alternative embodiment in which the catheter shaft 111 has a diagonal seam 130 formed by tubular members 131, 132 with overlapping diagonal ends. The lap-joined diagonal seam 130, although not as low profile as the butt-joined diagonal seam 120, still provides an improved flexibility transition in which the overall volume of softer material of the distal tubular member 132 gradually increases along the entire length of the bond. The stiffness increase caused by overlapping the ends of the tubular members is more gradual than the stiffness increase that would have resulted if one or both mating ends of the tubular members 131, 132 had a conventional straight end. FIG. 12 is a transverse cross section taken through the diagonal bond between the diagonal ends of the tubular members 131, 132, along line 12-12 of FIG. 11.

In a presently preferred embodiment, the inner tubular member 118 is a trilayer tubular member having an inner layer typically formed of a lubricous material such as HDPE, a middle tie layer such as a functionalized polyolefin adhesive polymer, and an outer readily bondable layer such as a polyamide such as a nylon or a polyether block amide (PEBAX). The diagonal seam between two segments of the inner tubular member provides a stiffness transition typically by transitioning from a trilayer having an outer layer of a higher Shore durometer hardness material to a trilayer having an outer layer of a compatible but lower Shore durometer hardness material. For example, in one embodiment, the diagonal seam 120 is between a proximal segment 124 of a trilayer of HDPE, tie layer polymer, and PEBAX 63D outer layer to a distal segment 125 of a trilayer of HDPE, tie layer polymer, and PEBAX 35D outer layer, although a variety of suitable materials may be used. In the illustrated embodiment, the distal tip member 119 is a single layer tubular member, typically being formed of a polymer fusion bond compatible an adjacent layer of the inner tubular member 118. However, a variety of suitable tip members can be used including multilayer tip members. The distal tip member is generally configured to provide flexibility and is typically formed of a softer polymeric material than the adjacent section of the inner tubular member.

In one embodiment, the diagonal seam 120, 130 provides directionality to the bending of the shaft when the tubular members bonded together by the diagonal seam have a different flexibility. For example, the shaft 111 will bend/deflect towards the side of the diagonal seam having more of a lower Shore durometer hardness material than the opposite side of the diagonal seam. Thus, the shaft will curve inwardly on the side of the shaft having the proximal end 121 of the diagonal seam 120 between the inner tubular member 118 and the soft tip member 119 (formed at least in part of a polymeric material having a lower Shore durometer hardness than the inner tubular member 118). In an embodiment in which the tubular members are not of a different flexibility at the diagonal seam, the diagonal seam does not provide bending directionality, although the diagonal seam nonetheless provides the advantages of a strong but relatively low profile joint as discussed above.

The dimensions of catheters of the invention are determined largely by the size of the balloon and guidewire to be

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employed, the catheter type, and the size of the artery or other body lumen through which the catheter must pass, or the size of the stent being delivered. Typically, the outer tubular member 17/117 has an outer diameter of about 0.025 to about 0.04 inch (0.064 to 0.10 cm), usually about 0.037 inch (0.094 cm), and the wall thickness of the outer tubular member 17 can vary from about 0.002 to about 0.008 inch (0.0051 to 0.02 cm), typically about 0.003 to 0.005 inch (0.0076 to 0.013 cm). The inner tubular member 18/118 typically has an inner diameter of about 0.01 to about 0.018 inch (0.025 to 0.046 cm), usually about 0.016 inch (0.04 cm), and a wall thickness of about 0.004 to about 0.008 inch (0.01 to 0.02 cm). The overall length of the catheter 10, 110 may range from about 100 to about 150 cm, and is typically about 143 cm. Preferably, balloon 14, 114 has a length about 0.8 cm to about 6 cm, and an inflated working diameter of about 2 to about 10 mm.

Although the tubular members of the shafts 11, 111 are illustrated as having uniform inner and outer diameters and wall thicknesses, it should be understood that they can have tapering inner or outer diameters at various locations along the length of the shaft. For example, the tip member 19, 119 can have a thinner wall thickness than the end section of the inner tubular member to be bonded thereto, in which case the inner surfaces are typically aligned and the outer surface of the inner member is caused to flow distally during bonding to smooth the outer surface at the junction.

The shaft outer and inner tubular members and tip member can be formed by conventional techniques, for example by extruding and necking materials already found useful in intravascular catheters such as polyethylene, polyvinyl chloride, polyesters, polyamides, polyimides, polyurethanes, and composite materials. The various components may be joined using conventional bonding methods such as by fusion bonding or use of adhesives. The inner tubular member and outer tubular member are typically multilayered tubing, or sections of tubing joined end-to-end, as is conventionally known for balloon catheter shafts. Although the shaft is illustrated as having an inner and outer tubular member, a variety of suitable shaft configurations may be used including a dual lumen extruded shaft having a side-by-side lumens extruded therein. Although the embodiment illustrated in FIG. 1 is an over-the-wire type balloon catheter having the guidewire lumen extending from the guidewire distal port at the catheter distal end to a guidewire proximal port at the proximal end of the shaft, the catheter can alternatively be a rapid exchange catheter having a relatively short guidewire lumen extending from the distal end port to a guidewire proximal port spaced distally from the proximal end of the catheter shaft. Additionally, the outer tubular member typically includes supporting members including a high strength member such as a hypotube in the proximal shaft section and/or across the guidewire proximal port in the rapid exchange embodiment (not shown).

While the present invention is described herein in terms of certain preferred embodiments, those skilled in the art will recognize that various modifications and improvements may be made to the invention without departing from the scope thereof. For example, although illustrated in terms of embodiments in which the distal coupling band member is on the guidewire lumen-defining inner tubular member of the balloon catheter, the lumen surrounded by the distal coupling band member can have a variety of suitable designs and uses (e.g., drug delivery) in addition to or as an alternative to use as a guidewire lumen. Similarly, the diagonal seam can be used to join shaft segments having a variety of uses and locations along a shaft of a variety of suitable catheter

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types. Moreover, although individual features of one embodiment of the invention may be discussed herein or shown in the drawings of the one embodiment and not in other embodiments, it should be apparent that individual features of one embodiment may be combined with one or more features of another embodiment or features from a plurality of embodiments.

What is claimed is:

1. A balloon catheter comprising:

a) an elongate tubular shaft including an outer tubular member having a proximal portion and a distal portion, the elongate tubular shaft including an inner tubular member having a distal length extending distally from the distal portion of the outer tubular member, the elongate tubular shaft having an inflation lumen and a guidewire lumen defined therein, the guidewire lumen extending along at least the distal length of the inner tubular member;

a) a distal end section coupled to a distal end of the inner tubular member, the distal end section having a proximal end and a distal end; and

a) a balloon having a proximal portion, a distal portion and a working length therebetween, the proximal portion of the balloon sealingly coupled to the distal portion of the outer tubular member, the distal portion of the balloon sealingly coupled to the distal end section, the balloon defining an inner chamber in fluid communication with the inflation lumen;

wherein the inner tubular member comprises a trilayer tubular member, and the proximal end of the distal end section is disposed within the inner chamber.

2. The balloon catheter according to claim 1, wherein the inner tubular member and the distal end section are coupled by a lap-joint or a butt-joint.

3. The balloon catheter according to claim 1, wherein the inner tubular member and the distal end section are coupled by a lap-joint.

4. The balloon catheter according to claim 3, wherein the distal end section overlaps the inner tubular member at the lap-joint.

5. The balloon catheter according to claim 3, wherein the inner tubular member overlaps the distal end section at the lap-joint.

6. The balloon catheter according to claim 1, wherein the distal end section is more flexible than the inner tubular member.

7. The balloon catheter according to claim 1, wherein the distal end section comprises a softer polymeric material than a material of the inner tubular member.

8. The balloon catheter according to claim 1, wherein the distal end section includes a distal tip member.

9. The balloon catheter according to claim 8, wherein the distal tip member comprises at least a first material and the distal length of the inner tubular member comprises at least a second material, wherein the first material is more flexible than the second material.

10. The balloon catheter according to claim 9, wherein the first material has a Shore durometer hardness between about 35D and about 70D.

11. The balloon catheter according to claim 8, wherein a distal end of the distal tip member has an atraumatic configuration.

12. The balloon catheter according to claim 1, further comprising a medical device coupled to the balloon.

13. The balloon catheter according to claim 1, further comprising at least one radiopaque marker coupled to the inner tubular member.

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14. The balloon catheter according to claim 1, further comprising at least one radiopaque marker coupled to the distal end section.

15. The balloon catheter according to claim 1, further comprising at least one radiopaque marker coupled to the distal end section and at least one radiopaque marker coupled to the inner tubular member.

16. The balloon catheter according to claim 1, wherein the proximal portion of the balloon includes a proximal skirt section and a proximal cone section and the distal portion of the balloon includes a distal skirt section and a distal cone section.

17. A balloon catheter comprising:

an elongate tubular shaft including an outer tubular member having a proximal portion and a distal portion, the elongate tubular shaft including an inner tubular member having a distal end, the elongate tubular shaft having an inflation lumen and a guidewire lumen defined therein, the guidewire lumen extending to the distal end of the inner tubular member;

a distal end section coupled to the distal end of the inner tubular member, the distal end section having a proximal end and a distal end; and

a balloon having a proximal portion, a distal portion and a working length therebetween, the proximal portion of the balloon sealingly coupled to the distal portion of the outer tubular member, the distal portion of the balloon sealingly coupled to the distal end section, the balloon defining an inner chamber in fluid communication with the inflation lumen;

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wherein the inner tubular member comprises a trilayer tubular member, and the proximal end of the distal end section is disposed proximate the distal portion of the outer tubular member.

18. The balloon catheter according to claim 17, wherein the proximal end of the distal end section is disposed proximal the distal end of the inner tubular member.

19. The balloon catheter according to claim 17, wherein the proximal end of the distal end section is disposed within the inner chamber.

20. The balloon catheter according to claim 17, wherein the distal end section and the distal end of the inner tubular member are coupled by a bond along a diagonal seam therebetween.

21. The balloon catheter according to claim 1, wherein the trilayer tubular member comprises an inner layer including a lubricous material.

22. The balloon catheter according to claim 1, wherein the trilayer tubular member comprises a middle tie layer.

23. The balloon catheter according to claim 1, wherein the trilayer tubular member comprises an outer layer thermally bondable to the distal end section.

24. The balloon catheter according to claim 23, wherein the outer layer comprises polyether block amide.

25. The balloon catheter according to claim 8, wherein the distal tip member comprises a single layer tubular member.

26. The balloon catheter according to claim 25, wherein the single layer tubular member comprises polyether block amide.

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